marketing of the products subject to those NDAs. Additional ANDAs that refer to these products may also be approved by the agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: September 24, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–23035 Filed 9–30–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0484]

Preparation for International Conference on Harmonization Meetings in Brussels, Belgium; Public Meeting; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting; correction.

SUMMARY: The Food and Drug Administration (FDA) is announcing a correction to the notice of a public meeting entitled ''Preparation for International Conference on Harmonization Meetings in Brussels, Belgium; Public Meeting.'' This meeting was announced in the **Federal Register** of September 16, 2008 (73 FR 53428). The correction is being made to reflect changes in the *Summary*, *Date and Time*, *Location*, *Contact Person*, *Background*, and *Agenda* portions of the document.

FOR FURTHER INFORMATION CONTACT: Tammie Jo Bell, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, by email: *Tammie.Bell2@fda.hhs.gov* or fax: 301–827–0003.

SUPPLEMENTARY INFORMATION: The FDA is correcting a notice published in the **Federal Register** of September 16, 2008 (73 FR 53428), announcing a meeting entitled ''Preparation for International Conference on Harmonization Meetings in Brussels, Belgium.'' This corrected notice is being published in its entirety:

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled ''Preparation for International Conference on Harmonization Meetings in Brussels, Belgium'' to provide information and receive comments on the International Conference on Harmonization (ICH) as well as the upcoming meetings in Brussels, Belgium. The topics to be discussed are the topics for discussion at the forthcoming ICH Steering Committee Meeting. The purpose of the meeting is to solicit public input prior to the next Steering Committee and Expert Working Groups meetings in Brussels, Belgium, November 10 to 13, 2008, at which discussion of the topics underway and the future of ICH will continue, as well as provide comprehensive updates of the various ICH topics.

Date and Time: The meeting will be held on Tuesday, October 21, 2008, from 2:30 p.m. to 5:30 p.m.

Location: The meeting will be held at 5600 Fishers Lane, 3rd floor, Conference Rooms D and E, Rockville, MD 20857. For security reasons, all attendees are asked to arrive no later than 2:15 p.m., as you will be escorted from the front entrance of 5600 Fishers Lane to Conference Rooms D and E.

Contact Person: All participants must register with Tammie Jo Bell, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, by email: *Tammie.Bell2@fda.hhs.gov* or fax: 301–827–0003.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number), written material, and requests to make oral presentation, to the contact person by October 14, 2008.

If you need special accommodations due to a disability, please contact Tammie Jo Bell at least 7 days in advance.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–66, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Background: The ICH was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan, and the United States without compromising the regulatory obligations of safety and effectiveness.

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for medical product development among regulatory agencies. ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. ICH is concerned with harmonization among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labor and Welfare; the Japanese Pharmaceutical Manufactures Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA). The ICH Steering Committee includes representatives from each of the ICH sponsors and Health Canada, the European Free Trade Area and the World Health Organization. The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the three ICH regions.

The current ICH process and structure can be found at the following Web site: *http://www.ich.org*.

Interested persons may present data, information, or views orally or in writing, on issues pending at the public meeting. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person by October 14, 2008, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses, phone number, fax, and email of proposed participants, and an indication of the approximate time requested to make their presentation.

Agenda: The agenda for the public meeting will be made available via the internet at *http://www.fda.gov/cder/meeting/ICH_20081021.htm*.

Dated: September 26, 2008.

Jeffrey Shuren,

Asssociate Commissioner for Policy and Planning.

[FR Doc. E8–23120 Filed 9–30–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0043]

[FDA No. 225–08–8004]

Memorandum of Agreement Between the Food and Drug Administration, the National Cancer Institute, a Part of the National Institutes of Health, and the CRIX International Association

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration FDA) is providing notice of a memorandum of agreement (MOA) between FDA, the National Cancer Institute (NCI) and CRIX International Association. The purpose of the MOA is to establish a public-private partnership to pilot the use of a nonprofit organization to manage the production instance of the Federal Investigator Registry of Biomedical Information Research Data (FIREBIRD) system as a vehicle for secure, rapid and efficient electronic exchange of clinical investigator credentialing information among clinical investigators at trial sites, sponsors (including NCI), and FDA; and to continue the development of FIREBIRD to fulfill the requirements of FDA and sponsors (including the NCI).

DATES: The agreement became effective August 28, 2008.

FOR FURTHER INFORMATION CONTACT:

Randy Levin, Director for Health and Regulatory Data Standards (HF–18), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7784;

George Komatsoulis, Chief Operating Officer, Center for Bioinformatics, National Cancer Institute, 8800 Rockville Pike, Bethesda, MD 20892–8505, 301–451–2881; and

James L. Bland, Project Officer, CRIX International Association, 1195 Freedom Dr., Reston, VA 20190, 703–577–8788.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOA.

Dated: September 24, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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